UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	
	Chapter 11
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtor.[1]	**(Jointly Administered)**

FOURTH AND FINAL MONITOR REPORT

Comes now, Thomas J. Vilsack, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This fourth and final Monitor Report will include a reference to actions taken from the time of the undersigned's appointment as Monitor to the date of this filing in relationship to the compliance with the terms and conditions of the Voluntary Injunction by Purdue Pharma L.P. , a general reference to the documents and records reviewed as reported in the Initial Monitor's Report, the Second Monitor's Report and the Third Monitor's Report, to recommendations provided to Purdue Pharma L.P. and the company's responses thereto and implementation thereof, and to the conclusion reached that Purdue Pharma L.P. and the Initial Covered Sackler Persons have made during the period of undersigned's service as Monitor a good faith effort to comply with the terms and conditions of the Voluntary Injunction.

1 The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

During the undersigned service as Monitor the officials at Purdue Pharma L.P. have been responsive and cooperative in providing documents in a timely and complete fashion, in arranging for multiple interviews with key officials and in providing extensive documentation at my request reflecting business activities at Purdue Pharma L.P.

INJUNCTION

1. On November 6, 2019, the Bankruptcy Court entered a Preliminary Injunction Order as part of the above entitled bankruptcy case. The Preliminary Injunction Order included, as Appendix I, a Voluntary Injunction ("Injunction") pursuant to which Purdue Pharma L.P., on its behalf and on behalf of its direct and indirect subsidiaries and general partner (collectively "Purdue Pharma"), agreed, in part, to retain a Monitor with the responsibility to report on compliance with the terms of the Injunction every 90 days. The Preliminary Injunction has been amended numerous times, but the Voluntary Injunction has remained the same each time. A copy of the currently operative Preliminary Injunction order, entered by the Bankruptcy Court on October 30, 2020, including the Injunction was attached as Exhibit One to the Initial Monitor Report.

2. Under the Injunction Purdue Pharma agreed to each and every one of the following:

a. Under Part II Section A paragraph 1 a-h of the Injunction, Purdue Pharma agreed to restrict the dissemination of information by Purdue Pharma or a Third Party on its behalf that was either likely or intended to influence prescribing practices of health care providers (HCPs) in favor of prescribing greater amounts, quantities, doses and/or strengths opioid products.

b. Under Part II Section B paragraph 1 of the Injunction, Purdue Pharma agreed not to provide any financial incentive to its sales and marketing employees or take any disciplinary

action against any of its sales and marketing employees that was directly based on or tied to the sales volume or quotas for opioid products unless otherwise permitted by the above entitled Bankruptcy Court.

c. Under Part II Section B paragraph 2 of the Injunction, Purdue Pharma also agreed not to offer to pay any remuneration directly or through a Third Party to any person or entity for the prescribing, sale, use, or distribution of opioid products other than the use of rebates or chargebacks.

d. Under Part II Section C paragraph 1 and 6 of the Injunction, Purdue Pharma agreed not to provide any financial support or In-Kind support to any Third Party, medical society, or patient advocate group for the purpose of promoting opioid or opioid products including but not limited to the following: providing links to Third Party websites related to opioids or opioid products, knowingly using a Third Party to engage in activity prohibited by the Injunction, enabling or advocating for the appointment of a director, board member, employee, agent, or officer to serve in a similar capacity concurrently in any entity that promotes opioids, opioid products or opioid related treatment of pain or opioid related side effects except as authorized under the Part II Section C paragraphs 1 and 7 of the Injunction.

e. Under Part II Section D paragraph 1 of the Injunction, Purdue Pharma agreed not directly or through a Third Party lobby for the enactment of any federal, state, or local legislation or for the promulgation of any rule or regulation that encourages or requires a health care provider to use opioids or sanctions a health care provider for the failure to prescribe or use opioids for the treatment of pain subject only to the limitations set forth in Part II paragraph D (4) of the Injunction.

f. Under Part II Section D paragraph 2, Purdue Pharma agreed not to directly or through a Third Party lobby against the enactment of any federal, state or local legislation or against the promulgation of any rule or regulation encouraging non-pharmacological or non-opioid pharmacologic therapy for the treatment of pain, the use of lowest possible dosages where appropriate of opioids or immediate release opioids, a limitation on an initial prescription of an opioid product, reasonable preconditions including testing before prescribing an opioid product, the use of or payment for evidence based treatments for opioid use disorder, and the implementation of a proper disposal system subject only to the limitations set forth in Part II Section D paragraph 4 of the Injunction.

g. Under Part II Section D paragraph 3 of the Injunction, Purdue Pharma agreed not to directly or through a Third-Party lobby against the enactment of any federal, state or local legislation or against the promulgation of any rule or regulation that would limit the operation or use of PDMPs (Prescription Monitoring Program) including any requirement mandating the use of same before prescribing any opioid or opioid product.

h. Under Part II Section E of the Injunction, Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017 concerning a ban on high doses of prescription and transmucosal opioids exceeding 90 morphine milligram equivalents.

i. Under Part II Section F paragraph 1 of the Injunction, Purdue Pharma agreed it would not directly or through a Third Party promote a savings card, voucher, coupons, or rebates programs to any health care provider for any opioid product or provide financial support to a Third Party to circumvent any such restriction. However, Purdue Pharma is authorized to provide

savings cards, vouchers, coupons or rebate programs, including point-of-dispense programs, in response to requests or on its website under the Injunction.

j. Under Part II Section G paragraph 1 a-d of the Injunction, Purdue Pharma agreed to operate an effective monitoring and reporting system to detect suspicious orders and possible diversion of opioids and opioid products by a direct customer or identify whether a downstream customer poses a material risk of diversion.

k. Under Part II Section G paragraph 2 of the Injunction, Purdue Pharma agreed to promptly provide reasonable assistance to law enforcement agencies involved in investigations of potential diversions or suspicious circumstances involving Purdue Pharma opioid products.

l. Under Part II Section G paragraph 3 of the Injunction, Purdue Pharma agreed that when and if one or more of the three largest pharmaceutical distributors establishes a system to aggregate transaction data involving the sale of opioid products and/or reports of suspicious orders Purdue Pharma would provide information into that system to the extent available and feasible, provided that the system is designed to use information provided by manufacturers of opioid products.

m. Under Part II Section G paragraph 4 of the Injunction, Purdue Pharma agreed to refrain from acting as a distributor of opioid products (aside from rescue and treatment medications) directly to a retail pharmacy or health care provider that would require it to be registered as a distributor under the Controlled Substances Act unless otherwise required by local, state, or federal law.

n. Under Part II Section I of the Injunction, members of the Sackler family as identified and described in Part I Section K, as Initial Covered Sackler Person, agreed not to be actively engaged in the opioid business in the United States other than by virtue of their

ownership interest in Purdue Pharma and that they would individually or collectively take no action to interfere with Purdue Pharma's responsibilities and duties under the Injunction.

MONITOR AGREEMENT

3. On February 13, 2020, the undersigned and Purdue Pharma executed the Purdue Monitor Agreement, which was attached as Exhibit Two to the Initial Monitor Report.

MONITOR ACTIVITIES

4. In performance of the duties of Monitor the undersigned Monitor did the following:

a. interviewed company officials,

b. retained experts,

c. reviewed the following documents, sites, information and records:

i. Purdue Pharma social media sites,

ii. Federal Drug Administration guidance and filings,

iii. state and federal lobbying reports and consultant agreements,

iv. package inserts, medication guides, labeling and prescribing information for branded opioid products manufactured and sold by Purdue Pharma,

v. federal and state spend reports and Sunshine Act reports,

vi. Purdue Pharma production and sales quotas for branded opioid products,

vii. Purdue Pharma financial records,

viii. relevant correspondence and emails related to negotiations obtaining, retaining or modifying formulary status,

ix. sales and marketing expense records,

x. gift and contribution records,

xi. suspicious order monitoring reports,

xii. chargeback reports,

xiii. standard operating procedures for suspicious order monitoring, threshold calculations, downstream customer monitoring and chargeback reports,

xiv. savings program and voucher materials,

xv. due diligence and annual questionnaires from wholesalers and distributors of branded opioid products and generic opioid products and from a select few wholesalers more detailed documentation of the due diligence efforts,

xvi. Drug Enforcement Agency reports filed in connection with suspicious order monitoring efforts,

xvii. customer call records,

xviii. business plans,

xix. wholesaler and distributor scorecards,

xx. emails from Purdue officials to the undersigned Monitor containing information requested by the undersigned,

xxi. records outlining rebate, administrative and service fees, discounts, inventory maintenance fees and other financial remuneration methods used by Purdue Pharma,

xxii. information related to the development and use of thresholds and/or algorithms used in the suspicious order monitoring systems used at Purdue Pharma,

xxiii. Purdue Pharma customer websites,

xxiv. industry newsletters and publications,

xxv. Drug Enforcement Agency Guidance and communications,

xxvi. employee training materials,

xxvii. Purdue Pharma's Code of Ethics,

xxviii. research project files,

xxix. post-marketing studies documentation,

xxx. records relating to grants and contributions made by Purdue Pharma,

xxxi. product catalogues,

xxxii. reports of inquiries to Purdue Pharma Medical Affairs department, and

xxxiii. criteria for the awarding of salary increases and bonus awards.

REPORTS, RECOMMENDATIONS AND COMPLIANCE

5. The undersigned Monitor filed three timely Reports: an Initial Report, a Second Report, and a Third Report that contained a series of recommendations formulated with the assistance of experts retained by the undersigned and agreed upon and implemented by Purdue Pharma. The recommendations can be found in the following paragraphs of the aforementioned reports:

a. paragraphs 48, 55, 58, 63, 101, 143, 144, 156, 159, 169, 170, 171, and 173 of the Initial Report,

b. paragraphs 31, 70, 71, 72, 76, 77, 90, and 94 of the Second Report, and

c. paragraphs 12, 13, 17, 19, 44 and 45 of the Third Report.

6. The aforementioned recommendations involved steps taken by Purdue Pharma that complied with the requirements of the Injunction and improved or bolstered the efforts by Purdue Pharma in the following areas:

a. handling of situations where the third-party salesforce retained by Purdue Pharma to market non-opioid products dealt with customers who in the past had purchased opioid products thereby avoiding a violation of the ban against promotion contained in the Injunction,

b. the use of data with appropriate warnings and alerts developed in conjunction with FDA required research that if published without said warnings and alerts in a subsequent scientific journal might have violated the ban against promotion contained in the Injunction,

c. maintaining consistency in the use of warning and cautionary language related to the use of opioids and risks associated with opioids in all public facing communications coming from Purdue Pharma,

d. clarifying that top line opioid product sales or volume would not be used as a factor in calculating salaries or bonuses for Purdue Pharma personnel,

e. strengthening the Purdue Pharma suspicious order monitoring system, threshold system and chargeback review system used at Purdue Pharma,

f. guaranteeing that the lobbyists hired in [22] states and at the federal level abide by the probations against lobbying for laws and rules that might encourage or require the use of opioids and opioid products,

g. calculating, providing or paying rebates, remunerations and other financial payments or discounts consistent with good business practice and with the terms and conditions of the Injunction, and

h. monitoring the involvement in any membership organization where the work could be attributed to Purdue Pharma thereby violating the ban against lobbying under the terms and conditions of the Injunction.

STEPS TAKEN SINCE FILING OF THIRD REPORT

7. The following steps have been taken since the filing of the Third Report by the undersigned Monitor that included a review of:

a. records outlining charitable and community contributions made by Purdue Pharma during 2020,

b. documents outlining any changes in formulary status for Purdue Pharma involving any managed care or group purchasing organization in the last quarter of 2020,

c. monthly financial reports,

d. documents related to any change in the language used in package inserts, mediation guides, boxed warnings, or prescribing information for branded opioid products,

e. monthly Suspicious Order Monitoring reports,

f. weekly reports to the DEA of orders of interest identified by the Purdue Pharma Suspicious Order Monitoring program,

g. monthly chargeback reports,

h. documentation of the investigations conducted of pended orders flagged by the Suspicious Order Monitoring program,

i. a chart reflecting market share for OxyContin over the last year,

j. state lobbying reports for the last quarter of 2020.

k. Outlier Reports centered on pharmacies identified under the revised chargeback review system established at Purdue Pharma,

l. follow up memos and emails responding to pharmacies identified in the monthly Outlier Reports,

m. a proposed Standard Operating Procedure for Downstream Customer Due Diligence,

n. state and federal lobbying firms' certifications of compliance with the provisions of the Injunction,

o. emails related to DEA referrals,

p. sales force certifications of compliance,

q. fee schedule noting changes in fees for major wholesalers and distributors, and

r. Due Diligence Questionnaires and Annual Reports.

PROMOTION PROHIBITED - COMPLIANCE

8. The undersigned Monitor has found that from the time of his appointment to the present time, Purdue Pharma has complied with the terms and conditions of the Injunction relating to a prohibition against the marketing of opioid products and in support of that conclusion offers the following:

a. Purdue Pharma disbanded its salesforce for branded opioid products in 2018 and it remains disbanded.

b. Purdue's sales of branded opioid products in volume and in value remains significantly below volume and value amounts from 2017 when the salesforce and promotional activities were in place.

c. The salesforce employed for non-opioid products has certified on a quarterly basis that each member of the salesforce since the Injunction was put in place has not promoted or marketed opioid products and that they have directed any and all inquiries about said products to the Medical Affairs department of Purdue Pharma.

d. A review of social media accounts and industry publications failed to uncover any promotional or marketing information for any branded opioid product manufactured and/or sold by Purdue Pharma since the Injunction was put in place. These sites did include the same warnings relating to the risks of abuse, misuse or over use of opioid products found in the package inserts, medication guides and prescribing information available for each branded

product. There was no evidence of any social media optimization being used by Purdue Pharma to market the branded opioid products offered by Purdue Pharma.

e. A multiple linear regressive analysis of drug utilization fees paid by Purdue Pharma was conducted by Health Data Services ("HDS"), a company that provides similar analyses for hospitals. Over 100 financial documents were provided to HDS by Purdue Pharma involving dealings with State Medicaid Departments, wholesalers, distributors, pharmacy benefit managers and managed care organizations. HDS concluded following its review that "there was no statistical evidence that Purdue Pharma is incentivizing sales volumes through increasing average fees paid per unit".

f. Purdue Pharma commissioned a study conducted by a third-party vendor to establish the fair market value of administrative fees paid by Purdue Pharma which concluded that the fees were within industry standards and were not set to promote the use, sale, prescribing or distribution of opioids or opioid products.

g. Even in situations where Purdue did offer to increase the fees within the fair market value range in order to preserve formulary status, the increased fees were an insufficient incentive to prevent the change in status or the loss of market share.

h. Purdue Pharma's federal Spend Reports and Sunshine Act reports did not list any expenditure that would be considered, as in the past, of a payment primarily designed to promote the use of opioids by health care professionals in the care and treatment of their patients.

i. The FDA website and docket related to opioids and opioid products has not contained any statement made or position taken by Purdue Pharma that could be construed or interpreted as promotion of the use opioids or opioid products.

j. The market share of OxyContin has declined from what it had been prior to the Injunction.

k. Purdue Pharma has lost formulary status from a number of managed care operations or Pharmacy Benefit Management plans.

l. Purdue Pharma's manufacturing and production quotes for opioids or opioid products and ingredients have remained below 2017-2018 levels.

BONUS, SALARIES AND INCENTIVES

9. The undersigned has found from the time of the Order granting the Injunction to the present, Purdue Pharma has complied with the terms and conditions of the Injunction related to not using top line opioid sales figures or volume figures as a factor or criteria for fixing salaries or awarding bonuses or other financial incentives and in support of that conclusion offers the following:

a. Purdue Pharma changed the method and factors used in fixing salaries, bonuses and incentives for most employees in 2019 and 2020 Purdue Pharma to avoid using top line opioid sales or volume as a factor in fixing salaries and awarding bonuses and other incentives. In 2020, Purdue Pharma relied on these three factors in varying rations: value creation (40%), innovation and efficiency (50%) and people and culture (10%) to make decisions related to salaries, bonuses and other incentives. Purdue Pharma is expected to rely on the same factors in 2021.

b. For the 6 employees of the Market Access Team who handle sales to managed care organizations and group purchasing operations Purdue Pharma uses a slightly different system to provide salaries, bonuses, and incentives. There are two factors involved in the process in the Market Access Incentive Compensation Plan used to determine for that 6 member team the

qualifications for bonuses or incentives: performance and corporate performance. Neither factor involves the top line for opioid sales value or volume as a factor in fixing salaries or awarding bonuses or incentives.

GRANTS AND IN KIND SUPPORT

10. The undersigned has found from the time of the court order granting the Injunction to the present that Purdue Pharma has complied with the terms and conditions of the Injunction related to prohibition against providing financial support or in-kind support to any third party for the purpose of promoting opioid or opioid products and in support of that conclusion offers the following:

a. Personnel from the sales and marketing departments of Purdue Pharma are not involved in making decisions currently involving the awarding of any grants or in-kind contributions.

b. Grants and in-kind contributions are decided by virtue of a multi-disciplinary committee that includes personnel from the Law department and Ethics and Compliance departments.

c. Purdue Pharma prohibits making any contribution requested by any customer.

d. The nature of grants and in-kind contributions currently awarded by Purdue Pharma center on prevention of or treatment for opioid abuse or misuse.

THIRD PARTY PAYMENTS

11. The undersigned has found from the time of the court order granting the Injunction to the present, Purdue Pharma has complied with the terms and conditions of the Injunction related to the prohibition against Purdue Pharma making third party payments to

promote the use, sale, prescribing or distribution of opioids or opioid products and in support of that conclusion offers the following:

a. A review of the available Federal Spend reports for the applicable time reflect no payment that has been made to promote the use, sale, prescribing or distribution of opioids or opioid products.

SAVINGS PLANS AND VOUCHERS

12. The undersigned has found from the time of the Order granting the Injunction to the present that Purdue Pharma has compiled with the terms and conditions of the Injunction related to the limited use of savings plans or vouchers and in support of that conclusion offers the following:

a. A review of company records indicated that Purdue Pharma discontinued a savings plan for Butrans, an opioid product, because a generic less expensive product became available and a savings plan or voucher would be ineffective.

b. However, through a third-party vendor Purdue Pharma still offers savings plans allowed under the Injunction for its OxyContin and Hysingla products but the plans are modest in terms of savings and have a number of conditions and restrictions that make the plans ill-suited if the goal of the plans was to use them to promote the use of those two branded products.

SUSPICIOUS ORDER MONITORING

13. The undersigned has found from the time of the Order granting the Injunction to the present that Purdue Pharma has complied with the terms and conditions of the Injunction related to suspicious order monitoring and in support of that conclusion offers the following:

a. Purdue Pharma has implemented agreed upon recommendations made by the undersigned in the previously filed Reports in order to strengthen the suspicious order monitoring system including but not limited to:

i. expanding the staff dedicated to monitoring orders with the appropriate experience and training to improve the suspicious order monitoring system,

ii. accelerating the schedule of personal inspection visits to wholesalers and distributors as part of the effort to improve due diligence efforts,

iii. providing additional documentation related to any investigation of any order pended by the system designed by third party vendor retained by Purdue Pharma to identify orders that may be of unusual size, unusual frequency or which deviate from a normal purchasing pattern,

iv. making improvements to the development and use of the purchasing threshold or history for each customer and each drug purchased to provide an additional filter by which to better identify possible suspicious orders,

v. conducting more extensive investigations of any order flagged by the suspicious order monitoring system at Purdue Pharma, and documenting more thoroughly the reasoning behind the decision to decline to ship product or the decision to ship product,

vi. reporting now all orders to the Drug Enforcement Agency flagged by the suspicious order algorithm-based monitoring system as being of possible unusual size, unusual frequency or deviation from normal patterns,

vii. conducting review of the chargeback reports now on a monthly instead of quarterly basis as part of the effort to strengthen efforts at detecting diversions of opioid and opioid products,

viii. examining more thoroughly the Due Diligence Questionnaires and Annual Reports submitted by wholesalers and distributors and refusing to fill pending orders until the forms are completely satisfactorily,

ix. developing an algorithm cloud-based system to better identify chargebacks that require additional investigation, and

x. developing an Outlier Report system for pharmacies flagged during the chargeback review system that identifies pharmacies that are being monitored by the DEA.

LOBBYING AND MEMBERSHIP

14. The undersigned has found from the time of the court order granting the Injunction to the present, Purdue Pharma has complied with the terms and conditions of the Injunction related to the restrictions on lobbying and in support of that conclusion offers the following:

a. Purdue Pharma implemented agreed upon recommendations related to lobbying made by the undersigned in the previously filed Reports in order to strengthen the prohibitions against unauthorized lobbying including but not limited to:

i. requiring lobbyists retained by Purdue Pharma at the state and federal level to certify quarterly compliance with the terms and conditions of the Injunction,

ii. directing lobbyists retained by Purdue Pharma at the federal and state level to report quarterly all bills which for which they lobbied on behalf of Purdue Pharma and the position taken as to each such bill, and

iii. agreeing that any official from Purdue Pharma serving Purdue Pharma or its interests on the board of any organization of which Purdue Pharma is a member or the individual serving Purdue Pharma is a member shall recuse himself or herself from any action or

vote on any issue brought before the board relating to lobbying for a bill or law that would help to promote the use of opioids or opioid products.

RECOMMENDATION

15. I would make an additional recommendation for Purdue Pharma to consider surrounding its Suspicious Order Monitoring system. Improvements have been instituted including better documentation of orders flagged as pended orders or orders of interest. Within that system, Purdue Pharma officials make requests for additional information to determine if orders should be shipped or if diversion is taking place downstream. In almost every case of follow up, Purdue Pharma officials accept the representations of officials from their customers. **To further strengthen that system of follow up I would recommend that monthly Purdue Pharma select a number of follow up cases in which Purdue Pharma would require additional back up information from the customer. This request should be defined to provide additional information and documentation of the basis and explanation of why a particular order should not be considered a suspicious order. Purdue Pharma agrees to this recommendation and will work to implement it.**

INITIAL COVERED SACKLER PERSONS

16. Under Part II, Section I of the Injunction the Initial Covered Sackler Person's were not to be actively engaged in the opioid business in the United States or interfere with compliance with the Injunction. Since the filing of the Initial Report one of the Initial Covered Sackler Persons, Jonathan D. Sackler, has died. Under Part II, Section I of the Injunction,the Estate of Jonathan D. Sackler will be substituted for Jonathan D. Sackler as an Initial Covered Sackler Person.

17. The undersigned Monitor received signed certifications from all the named Initial Covered Sackler Persons or their representatives certifying that none of the named Initial Covered Sackler Persons actively engaged in the opioid business in the United States and that each one has taken no action to interfere with compliance of the provisions of the Injunction.

Wherefore, the undersigned Monitor prays the Court accept this Fourth and Final Report of this Monitor and discharge this Monitor from further duties and responsibilities.

Thomas J. Vilsack

Thomas J. Vilsack
Monitor